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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,882	10/04/2000	Timothy Lang	A20-015	5846

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EXAMINER

LILLING, HERBERT J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/10/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,882

Applicant(s)

LANG ET AL.

Examiner

HERBERT J LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1651

1. Receipt is acknowledged of the election response filed August 31, 2001.
2. Claims 1-39 remain pending in this instant application.
3. Applicant has elected with traverse Group III, Claims 34-39, drawn to an agent for increasing levels of one or more fatty acids to the colon.

Claims 1-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

The restriction is proper in view of the serious burden to search and examine all of the claims which are drawn to food products classified in Class 426 whereas the "agent" is classified in Class 424 as a therapeutic use in a colon of an animal or human.

4. The following is a quotation of the **first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed since the terms "agent" and "agent derived from fiber extracts" lack any suitable description for the claimed substance. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, that is the terms or expressions "agent", "agent derived from" and "from fibre extract", is not a description of that material.

Thus, Claims 34-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a suitable indication of the "agent" as to the complete structure or identifying characteristics of the "agent" components, thus the description requirement has not been satisfied.

5. The following is a quotation of the **second paragraph of 35 U.S.C. 112**:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 34-39 are rendered vague and indefinite by the terms " agent" "derived from fibre extracts" because these terms, in and of itself, do not adequately delineate its metes and bounds. An "agent" or an extract is necessarily a product-by-process because the composition of the extract is only defined by the process of its preparation. Such product-by-process claims are intended to define products, which are otherwise difficult to define and/or distinguish from the prior art except, by the process of making. Since any given biological source contains thousands of extractable compounds, each with it's own particular extraction properties, the nature of the resulting extract will depend on the conditions of the extraction and the solvent used. For example, at what temperature is the extraction performed? Is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, or is it a squeezed extract? It is well accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of

active ingredients obtained, and, thus, on the ability of the extract to provide the desired functional effect(s) claimed and/or disclosed. Since the extract itself is clearly essential to the instantly claimed invention, the step(s) by which the claimed extract is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds". The scope of the instant claims with respect to these "agent(s) derived from fibre extracts" are vague and indefinite since one would not expect the components to be the same for different fruits or vegetables. See, e.g., the following decisions: *In re Hammack*, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); *In re Venezia* 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); *In re Goffe*, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); *In re Watson*, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); *In re Knowlton* 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: *In r Ste le*, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); *In re*

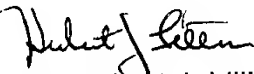
Art Unit: 1651

Moor 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975). Claims 34-39 fail to comply with the above decisions.

6. **No claim is allowed.** A search of the art cannot be properly made until the scope of the language of the claims make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds" as noted above.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
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Art Unit **1651**
May 08, 2002


Dr. Herbert J. Lilling
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